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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|----------------|----------------------|--------------------------|------------------|
| 09/760,810 | 01/17/2001 | Kjell Olmarker | 003300-737 | 4391 |
| 7 | 590 03/26/2002 | | | |
| Benton S. Duffett, Jr. BURNS, DOANE, SWECKER, & MATHIS, L.L.P. P.O. Box 1404 | | | EXAMINER | |
| | | | SEHARASEYON, JEGATHEESAN | |
| Alexandria, VA 22313-1404 | | ART UNIT | PAPER NUMBER | |
| | | | 1647 | 10 |
| | | | DATE MAILED: 03/26/2002 | 10 |

Please find below and/or attached an Office communication concerning this application or proceeding.

| <u> </u> | Application No. | Applicant(s) | | | | |
|---|--|--|--|--|--|--|
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| Office Action Summary | 09/760,810 | OLMARKER ET AL. | | | | |
| Omoc Addon Gammary | Examiner | Art Unit | | | | |
| The MAILING DATE of this communication app | Jegatheesan Seharaseyon ears on the cover sheet with the c | 1647 | | | | |
| Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| 1)⊠ Responsive to communication(s) filed on <u>07 A</u> | ugust 2001 . | | | | | |
| <u> </u> | s action is non-final. | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>1 and 2</u> is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6) Claim(s) is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) <u>1 and 2</u> are subject to restriction and/or election requirement. Application Papers | | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner. | | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | | |
| 12)☐ The oath or declaration is objected to by the Examiner. | | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | | |
| a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) | 5) Notice of Informal I | (PTO-413) Paper No(s) Patent Application (PTO-152) | | | | |

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DETAILED ACTION

- 1. This application contains the following patentably distinct TNF- α inhibitors.
- (a) metalloproteinase inhibitors excluding methylprenisolone
- (b) quinolones
- (c) corticosteroids
- (d) thalidomide
- (e) lazaroides
- (f) pentoxyphyllines
- (g) hydroxamic acid derivatives
- (h) carbocyclic acids
- (i) napthopyrans
- (j) amrinone
- (k) pimobendan
- (I) vesnarinone
- (m) phosphodiesterase III inhibitors
- (n) lactoferrin and lactoferrin derived analogs
- (o) melatonin, and bases or addition salts thereof

Applicant is required under 35 U.S.C. 121 to elect a single disclosed TNF- α inhibitors for prosecution on the merits to which the claims (1 and 2) shall be restricted to because of the improper Markush Group. M.P.E.P. 803.02:

"Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978); and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office

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to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility." In the instant application, the various TNF- α inhibitors do not share a common structural feature.

Applicant is advised the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 703-305-1112. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for

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the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

js March 21, 2002

JEFFREY STUCKER
PRIMARY EXAMINER